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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHIBUYA, MARK LANCE

ART UNIT PAPER NUMBER

1639

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,442

Applicant(s)

LIETZ, ERIC

Examiner

Mark L. Shibuya

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-51 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-24 and 27, drawn to methods for producing mutagenized polynucleotides from a target sequence, comprising at least one oligonucleotide.

Group II, claim(s) 25, 26, 28-38, drawn to methods for producing a library of mutagenized polynucleotides from a target sequence, comprising a library of oligonucleotides.

Group III, claim(s) 39-51, drawn to methods for producing a library of mutagenized polynucleotides from a double-stranded target sequence comprising a library of oligonucleotides.

The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking the groups I, II and III appears to be that they all relate to PCR methods for producing mutagenized polynucleotides of target sequences using two flanking primers and a third mutagenic oligonucleotide.

However, the reference of Kumar, EP 0466083 A2, (IDS 9/16/2002), throughout the publication, discloses a PCR derived method for producing mutagenized polynucleotides using two flanking primers and a third mutagenic primer (see claim 1 and figure 1). Therefore claim 1 is not novel. The flanking primers listed in p. 8, Table

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1, contain restriction sites and the primers are 20-25 nucleotides in length. Therefore claims 8 and 10-13 are not novel. The PCR conditions, as taught by Kumar at Example 1, p. 7, lines 28-36), include 2 minutes at 50 degrees C, after melting, which allows both annealing of the primers and extension by the polymerase and at least 3 minutes at 72 degrees C. Therefore, claims 16, 17 and 19 are not novel. Kumar discloses that more than one position of the target sequence can be mutated (see claim 14 of Kumar). Therefore claim 24 is not novel. Claims 2, 5, 6, 7, 9, 14, 15, 18 and 20-23 are dependent of claim 1, appear to be obvious in view of D1 and are considered to lack an inventive step (PCT Articles 33.2 and 33.3).

The use of fully random primers, according to claims 3 and 4 (an unknown target sequence implies the use of random primers) is not suggested in the reference of Kumar. However it is known from the reference of Arnold et al., WO 98/42832, (IDS 9/16/2002), which teaches throughout the publication, and especially at p. 8, lines 11-22 and Example 7, pp. 30-41, that random primers can be used to prime DNA synthesis in PCR reactions; and to introduce mutations during said PCR reactions (see the last two paragraph, p. 39). Therefore, claims are also considered as lacking an inventive step. Because the method of Arnold et al. implies the use of a library of random primers (p. 8, lines 11-22) and consequently the generation of a library of mutated sequences, the methods of claims 25 and 39, and their dependent claims, are considered as lacking an inventive step, (see PCT Article 33.3).

Therefore, the technical feature linking the inventions of Groups I-III does not constitute a special technical feature as defined by PCT Rule 113.2, as it does not define a contribution over the prior art. Accordingly, Groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Election of Species

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

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Applicant must elect a single and particular species of target sequence to be mutagenized.

Applicant must elect a single and particular species of length of an oligonucleotide.

Applicant must elect a single and particular species of temperature for primer extension.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

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Species of target sequence: claims 1, 6, 7, 25, 30, 31, and 39.

Species of length of oligonucleotide: claims 10-13, 32, 33, 44, and 45.

Species of temperature: claims 16-19, 36, and 49.

The following claim(s) are generic: Currently, claims 1, 25 and 39 are considered to be generic for the species.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The above references of Kumar and Arnold et al. teach target sequences, lengths of oligonucleotides, and temperatures for primer extension, so that these technical features do not constitute special technical features.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Shibuya
Examiner
Art Unit 1639

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